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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,696	01/23/2004	Paul Ashton	CDSI-P01-021	7672
28120 7590 05/25/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			05/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/763,696	<b>Applicant(s)</b> ASHTON, PAUL	
	<b>Examiner</b> Sharon E. Kennedy	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/29/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims require at least one agent in its salt form, however, the lists recited in the dependent claims recite drugs which are not salts, such as captopril, propranolol, etc. Further, claim 44 recites a "method of providing an agent having a particular solubility, about 10 mg/ml or less. However, the preamble requires the method to be the providing of a highly soluble agent. This is inconsistent and applicant must reconcile the body of the claim with the preamble. Claims 13-16, 37-39, 57-60 are further indefinite because the concentrations recited are dependent primarily upon the implant site of the device. Claim 67 is further vague and indefinite in view that it depends upon claims 62 or 63 instead of claims 65 or 66.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 11, 13-16, 23, 24, 29, 30, 35, 37-39, 43, 44, 49, 50, 55, 57-60, 64, 65, 67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Smith et al., US 5,378,475. Smith discloses the claimed invention. The abstract discloses the basic concept of the inner core or reservoir comprising the agent, the first coating layer, second coating layer, etc. The Smith reservoir 5 anticipates the claimed inner core, and various polymer skins are provided thereover. Regarding the particular drugs and solubilities, see, for example, column 11, lines 11+. Ganciclovir (GCV) is provided in an exemplified intraocular device. GCV is known to have a solubility of 4.3 mg/ml. In column 6, lines 18-25, the salt forms of drugs are expressly disclosed. Claims 13-16 are inherently anticipated in view that the amount of agent surrounding the outside of the outer polymer skin is a function of the environment surrounding the device.

Claims 1, 3, 44, 47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chen et al., US 5,902,598. Note the figures disclosing the various coatings and the compositions thereof in columns 7 and 8.

Claims 1, 2, 9, 20, 24, 25, 26, 27, 44, 45, 46, 49, 50, 65, 66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guo et al., US 6,375,972. Note drug matrix 114, the express disclosure of the agent in salt form (column 12, lines 48+), impermeable outer layer 210. Regarding claim 8, Guo discloses the generic matrix system in the background, column 2, lines 9+.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo '972. Guo figure 1 discloses outer layer 210 comprising more than 75% of the surface. Modifying the configuration of layer 210 is an obvious design choice yielding the predictable result of increasing or decreasing delivery rates.

Claims 4, 7, 8, 10, 17, 18, 19, 28, 31-34, 40, 41, 42, 48, 51-54, 61, 62, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo '972. The claimed polymers and their properties are conventional in the art and would be obvious to incorporate into the Guo device.

Claims 12, 36 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith '475. Smith discloses, for example gelatin as a bioerodible polymer. The

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claimed polymers and their properties are conventional in the art and would be obvious to incorporate into the Guo device.


### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant's various combinations of polymers, matrixes, bioerodible, non-bioerodible, etc., constitute various independent species as evidenced by the prior art and restriction is likely if examination continues to be burdensome. There appear to be about 20 distinct species disclosed and claimed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615